DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

4021. Misbranding of acetylsalicylic acid tablets, ophthalmic ointment, potassium iodide tablets, and rhinitis tablets. U. S. v. 4 Cartoned Bottles, etc. (F. D. C. No. 34671. Sample Nos. 36592–L, 70132–L to 70136–L, incl.)

LIBEL FILED: February 18, 1953, Southern District of Ohio.

ALLEGED SHIPMENT: Between August 22 and December 30, 1952, by Eli Lilly & Co., from Indianapolis, Ind.

PRODUCT: 4 cartoned bottles of 1 grain *acetylsalicylic acid tablets*, 133 cartoned bottles of 5 grain *acetylsalicylic acid tablets*, 22 cartoned tubes of *ophthalmic ointment*, 34 bottles of *potassium iodide tablets*, and 4 bottles of *rhinitis tablets* at Dayton, Ohio.

LABEL, IN PART: (Bottle) "100 Tablets * * * A. S. A. (Acetylsalicylic Acid, Lilly) 1 gr. (0.065 Gm.) * * * Dose—1 tablet as directed by the physician" and "Tablets * * * A. S. A. (Acetylsalicylic Acid, Lilly) 5 grs. (0.325 Gm.) * * * Adult Dose—1 to 3 tablets as directed by the physician"; (tube) "⅛ Ounce Ophthalmic Ointment * * * Atropine Sulfate 1 percent To be used as directed by the physician"; (bottle) "100 * * * Enseals (Timed Disintegrating Tablets, Lilly) Potassium Iodide 5 grs. (0.325 Gm.) * * * Adult Dose—1 or 2 'Enseals' as directed by the physician. Indiscriminate use may be dangerous" and "1000 Tablets * * * Rhinitis Full Strength * * * Each tablet contains: Camphor_____ ½ gr. : 0.0325 Gm. Quinine Sulfate_____ ½ gr. : 0.0325 Gm. Ext. Belladonna Root_____ ⅛ gr. : 0.0035 Gm. (Total Alkaloids, 1/960 gr.) Camphor being volatile, the exact quantity cannot be guaranteed. Adult Dose—1 or 2 tablets as directed by the physician. Indiscriminate use may be dangerous."

NATURE OF CHARGE: *Acetylsalicylic acid tablets* (1 grain and 5 grains), *potassium iodide tablets*, and *rhinitis tablets*. Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use.

Rhinitis tablets. Misbranding, Section 502 (a), the label designation "Tablets * * * Rhinitis" was false and misleading since such designation represented and suggested that the article was an adequate and effective remedy for rhinitis, whereas it was not an adequate and effective remedy for rhinitis.

Ophthalmic ointment. Misbranding, Section 503 (b) (4), the article was a drug subject to Section 503 (b) (1) (B), and the label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: March 21, 1953. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4022. Misbranding of methyltestosterone tablets, thyroid tablets, dextro-amphetamine sulfate tablets, methamphetamine hydrochloride tablets, and tablets containing a mixture of phenobarbital and mannitol hexanitrate. U. S. v. Rice M. Reavis, Jr. Plea of nolo contendere. Fine, $350. (F. D. C. No. 33709. Sample Nos. 16316–L, 16317–L, 16321–L, 16323–L to 16325–L, incl., 16327–L.)

INFORMATION FILED: October 16, 1952, Eastern District of Oklahoma, against Rice M. Reavis, Jr., a partner in the partnership of the Reavis Drug Co., Ardmore, Okla.

*See also No. 4021.

ALLEGED VIOLATION: On or about October 10, 11, 12, and 15, 1951, while a number of *methyltestosterone tablets, thyroid tablets, dextro-amphetamine sulfate tablets, methamphetamine hydrochloride tablets,* and *tablets containing a mixture of phenobarbital and mannitol hexanitrate* were being held for sale at the Reavis Drug Co., after shipment in interstate commerce, one bottle of *thyroid tablets* was caused to be dispensed in the original bottle in which the tablets had been shipped in interstate commerce, without the prescription of a physician, and various quantities of the other drugs were caused to be repacked and dispensed without prescriptions, which acts resulted in the drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the *thyroid tablets* failed to bear adequate directions for use. (The bottle in which the tablets had been shipped in interstate commerce bore no directions for use since it was exempt from such requirement by the statement on the label "Caution: To be dispensed only by or on the prescription of a physician." The act of causing the dispensing of the drug without a physician's prescription caused the exemption to expire.)

Further misbranding, Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of all of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), portions of the repackaged *methyltestosterone tablets* and *dextro-amphetamine sulfate tablets* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the repackaged *tablets containing a mixture of phenobarbital and mannitol hexanitrate* contained a chemical derivative of barbituric acid, namely, phenobarbital, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the tablets failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (2), the labeling of the repackaged *methamphetamine hydrochloride tablets* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: December 22, 1952. The defendant having entered a plea of nolo contendere, the court fined him $350.

4023. Misbranding of sulfadiazine tablets, thyroid tablets, and methamphetamine hydrochloride tablets. U. S. v. Alvin H. Weinstein. Plea of nolo contendere. Fine, $75. (F. D. C. No. 34360. Sample Nos. 12081–L, 12726–L, 12729–L.)

INFORMATION FILED: April 23, 1953, Northern District of Ohio, against Alvin H. Weinstein, acting manager for the Schwartz Drug Co., Toledo, Ohio.

ALLEGED VIOLATION: On or about March 13 and 18, 1952, while a number of *sulfadiazine tablets, thyroid tablets,* and *methamphetamine hydrochloride tablets* were being held for sale at the Schwartz Drug Co., after shipment in interstate commerce, the defendant caused various quantities of the drugs to